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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,420	11/28/2000	Steven K. Yoshinaga	A-579C	7508

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AMGEN INCORPORATED
MAIL STOP 27-4-A
ONE AMGEN CENTER DRIVE
THOUSAND OAKS, CA 91320-1799

EXAMINER	
ROARK, JESSICA H	

ART UNIT	PAPER NUMBER
1644	13

DATE MAILED: 08/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/728,420	YOSHINAGA ET AL.	
	Examin r	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-42* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment, filed 5/17/02 (Paper No. 10), is acknowledged.
Claim 2 has been amended.
Claims 1-42 *are pending.*

Sequence Compliance

2. Sequence compliance: The CRF, paper copy of the Sequence Listing and Statement that the CRF and Sequence Listing are identical, filed 5/17/02, has been found acceptable and entered.

3. The specification stands objected to under 37 CFR 1.821(d) because SEQ ID NOS are not disclosed in the specification adjacent referenced sequences. The changes introduced to the Figure Legends are acknowledged; however, sequence identifiers are also missing at least on pages 97 (MYPPPY and FDPPPF) and 111. *Appropriate correction is required.*

Applicant is requested to *carefully review the specification* for all protein sequences of 4 or more amino acids, in any form; and all nucleic acid sequences of 10 or more nucleotides.

Applicant is reminded that if any sequence described in either the body of the specification or figures is not represented in the sequence listing as either an individual SEQ ID NO or a range present within a SEQ ID NO; a substitute sequence listing, paper copy and CRF is required.

Drawings

4. Formal drawings have been submitted which fail to comply with 37 CFR 1.84.
Please see the enclosed form PTO-948.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. *The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.*

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ***ABANDONMENT*** *of the application.*

Restriction Requirement

5. Applicant's election with traverse of Group XXXVI with a species election of an antibody antagonist in Paper No. 10 is acknowledged.

After review of the traversal in Applicant's response, filed 5/17/02;
the Restriction Requirement set forth in Paper No. 8 is hereby VACATED.

The evidence provided by Applicant indicates that SEQ ID NO:12 is an internal fragment of SEQ ID NO:17. In addition, Applicant's argument with respect to the shared structure essential to a common utility is found convincing with respect to SEQ ID NO: 7 (murine B7RP1) and SEQ ID NOS:12 and 17 (human B7RP1).

Therefore, a new Restriction Requirement in view of the evidence pointed to by Applicant follows:

6. The following is again noted:

A) The dependency of several claims appears to be incorrect (e.g., claim 5 refers to the host cell of claim 3, but claim 3 is a nucleic acid; claim 14 refers to the antibody of claim 11, but claim 11 is a polypeptide). The restriction has been set forth based upon textual dependency in view of these inconsistencies. Applicant should carefully review the dependency of the instant claims and make the appropriate corrections.

Applicant's comments, filed 5/17/02, regarding the deference of the corrections until a Final Restriction requirement is issued are acknowledged.

B) The specification discloses B7RP1 polypeptides (SEQ ID NOS:7, 12 and 17, encoded by SEQ ID NOS:6, 11 and 16, respectively) and a CRP1 polypeptide (SEQ ID NO:2 encoded by SEQ ID NO:1). B7RP1 and CRP1 polypeptides possess a *distinct structure*. Further, because these polypeptides are structurally distinct; the polynucleotides encoding these polypeptides, the antibodies which bind each polypeptides and transgenic mammals expressing these polypeptides are also distinct. These structurally distinct products are subject to restriction, rather than election of species, because they do not share *a substantial structural feature essential to a common utility* (as per MPEP 803.02) *Therefore, the restriction has been set forth for each product as a separate group, irrespective of the format of the claims.* Further, a search drawn to B7RP1 is not co-extensive with a search for CRP1.

C) Method claims 24, 25, 26, 28, 30, 32, 33, 39 and 42 each employ structurally distinct products, as noted supra in B, that do not share *a substantial structural feature essential to a common utility*. Consequently, within a given claim methods are recited which differ at least with respect to the method steps because different products are utilized. *Therefore, the restriction has been set forth for each as a separate group, irrespective of the format of the claims*

7. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1 and 3-7, drawn to an isolated nucleotide sequence related to CRP1, vectors, host cells, and methods of producing the polypeptide; classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

II. Claims 2-7, drawn to an isolated nucleotide sequence related to B7RP1, vectors, host cells, and methods of producing the polypeptide; classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

III. Claims 8-9, 11 and 19-23, drawn to a polypeptide related to CRP1 encoded by SEQ ID NO:1, fragments and compositions thereof, and heterologous proteins comprising said polypeptide; classified in Class 530, subclasses 395, 837, and 866 and Class 424, subclass 184.1.

IV. Claims 8, 10, 12 and 19-23, drawn to a polypeptide related to B7RP1 encoded by SEQ ID NO:1, fragments and compositions thereof, and heterologous proteins comprising said polypeptide; classified in Class 530, subclasses 395, 837, and 866 and Class 424, subclass 184.1.

V. Claims 13-16 and 18, drawn to an antibody or fragment thereof which binds a polypeptide related to CRP1; classified in Class 530, subclass 387.3.

VI. Claims 13, 15-18, drawn to an antibody or fragment thereof which binds a polypeptide related to B7RP1; classified in Class 530, subclass 387.3.

VII. Claim 24, drawn to a method of treating or preventing a T cell mediated disorder by administering a polypeptide related to CRP1, classified in Class 514, subclass 885.

VIII. Claim 24, drawn to a method of treating or preventing a T cell mediated disorder by administering a polypeptide related to B7RP1, classified in Class 514, subclass 885.

IX. Claim 25, drawn to a method of diagnosing a T cell mediated disorder by detecting a polypeptide related to CRP1, classified in Class 435, subclass 7.1.

X. Claim 25, drawn to a method of diagnosing a T cell mediated disorder by detecting a polypeptide related to B7RP1, classified in Class 435, subclass 7.1.

XI. Claims 26-27, drawn to a method of identifying a test molecule which binds to a polypeptide related to CRP1, classified in Class 435, subclass 7.8.

XII. Claims 26-27, drawn to a method of identifying a test molecule which binds to a polypeptide related to B7RP1, classified in Class 435, subclass 7.8.

XIII. Claim 28, drawn to a method of regulating T cell activation by administering a nucleic acid related to CRP1, classified in Class 514, subclass 44.

XIV. Claim 28, drawn to a method of regulating T cell activation by administering a nucleic acid related to B7RP1, classified in Class 514, subclass 44.

XV. Claim 29, drawn to a transgenic non-human mammal comprising a nucleic acid molecule related to CRP1, classified in Class 800, subclass 13.

XVI. Claim 29, drawn to a transgenic non-human mammal comprising a nucleic acid molecule related to B7RP1, classified in Class 800, subclass 13.

XVII. Claims 30, 32-33 and 35-36, drawn to a method of suppressing an immune response/IgE production by administering an antagonist of a CRP1 polypeptide, classified in Class 424, subclass 143.1.

XVIII. Claims 30-34 and 36, drawn to a method of suppressing an immune response/IgE production by administering an antagonist of a B7RP1 polypeptide, classified in Class 424, subclass 143.1.

XIX. Claims 32-36, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of *both* a CPR1 polypeptide *and* the B7RP1 polypeptide, classified in Class 424, subclasses 143.1.

XX. Claims 32-33 and 35-38, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of the CPR1 polypeptide, and *further comprising* administering an antagonist of IgE, classified in Class 424, subclasses 143.1 and 145.1.

XXI. Claims 32-34 and 36-38, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of the B7RP1 polypeptide, and *further comprising* administering an antagonist of IgE, classified in Class 424, subclasses 143.1 and 145.1.

XXII. Claims 32-38, drawn to a method of decreasing IgE production and treating an IgE-mediated disorder by administering an antagonist of *both* a CPR1 polypeptide *and* a B7RP1 polypeptide, and *further comprising* administering an antagonist of IgE, classified in Class 424, subclasses 143.1 and 145.1.

XXIII. Claims 39 and 42, drawn to a method of enhancing an immune response by administering a B7RP1 polypeptide, classified in Class 424, subclass 184.1.

XXIV. Claims 39-40, drawn to a method of enhancing an immune response by administering a B7RP1 polypeptide and *further comprising* administering a CD28 agonist, classified in Class 424, subclass 193.1.

XXV. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering a B7RP1 polypeptide and *further comprising* administering B7.1, classified in Class 424, subclass 193.1.

XXVI. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering a B7RP1 polypeptide and *further comprising* administering B7.2, classified in Class 424, subclass 193.1.

XXVII. Claims 39 and 41, drawn to a method of enhancing an immune response by administering a B7RP1 polypeptide and *further comprising* administering B7.1 *and* B7.2, classified in Class 424, subclass 193.1.

XXVIII. Claim 39, drawn to a method of enhancing an immune response by administering an *agonist* of a B7RP1 polypeptide, classified in Class 514, subclass 885.

XXIX. Claims 39-40, drawn to a method of enhancing an immune response by administering an *agonist* of a B7RP1 polypeptide and *further comprising* administering a CD28 agonist, classified in Class 424, subclass 193.1.

XXX. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of a B7RP1 polypeptide and *further comprising* administering B7.1, classified in Class 424, subclass 193.1.

XXXI. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of a B7RP1 polypeptide and *further comprising* administering B7.2, classified in Class 424, subclass 193.1.

XXXII. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of a B7RP1 polypeptide and *further comprising* administering B7.1 and B7.2, classified in Class 424, subclass 193.1.

XXXIII. Claims 39 and 42, drawn to a method of enhancing an immune response by administering an *agonist* of a CRP1 polypeptide, classified in Class 514, subclass 885.

XXXIV. Claims 39-40, drawn to a method of enhancing an immune response by administering an *agonist* of a CRP1 polypeptide and *further comprising* administering a CD28 agonist, classified in Class 424, subclass 193.1.

XXXV. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering an *agonist* of a CRP1 polypeptide and *further comprising* administering B7.1, classified in Class 424, subclass 193.1.

XXXVI. Claims 39 and 41-42, drawn to a method of enhancing an immune response by administering an *agonist* of a CRP1 polypeptide and *further comprising* administering B7.2, classified in Class 424, subclass 193.1.

XXXVII. Claims 39 and 41, drawn to a method of enhancing an immune response by administering an *agonist* of a CRP1 polypeptide and *further comprising* administering B7.1 and B7.2, classified in Class 424, subclass 193.1.

The inventions are distinct because:

8. Groups I-VI and XV-XVI are different products. Nucleic acids, polypeptides, antibodies to the polypeptides and transgenic non-human mammals expressing the polypeptides differ with respect to their structures and physicochemical properties; therefore for these reasons and the reasons set forth supra in Section 6, each product is patentably distinct.

9. Groups (I and III/XV) and (II and IV/XVI), respectively, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case the proteins can be made using an amino acid synthesizer.
In the instant case the nucleic acids can also be used to produce the proteins, in addition to use in construction of non-human transgenics.

10. Groups VII-XIV and XVII-XXXVII are different methods. As noted supra, these methods utilize distinct products, requiring different method steps. In addition, methods of treating, diagnosing and identifying each differ with respect to ingredients, method steps, and endpoints. Therefore, each method is patentably distinct.

11. Groups (I and XIII), (II and XIV), (III and VII), (IV and VIII/XXIII-XXVII), (V and IX, XVII/XIX/XX/XXII/XXXII-XXXVII) and (VI and X/XVIII-XIX/XXI-XXII/XXVIII-XXXII), respectively, are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the nucleic acids can be used to express the proteins in a prokaryotic expression system, in addition to use in the gene therapy methods recited.
In the instant case, the polypeptides can be used to produce antibodies, in addition to the different methods of modulating an immune response recited.
In the instant case the antibodies can be used for affinity purification, in addition to the methods of treating and diagnosing recited.
Finally, it is note that each method recited is also recited as practicable with another materially different product.

12. Inventions (V and XI) and (VI and XII), respectively, are related as products and method of identifying said products. However, the method steps do not define the structure of the claimed products. Therefore, they are patentably distinct

13. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

14. This application contains claims directed to the following patentably distinct species of the claimed Invention II, XIV and XVI: wherein the B7RP-1 nucleotide sequence is:

A) SEQ ID NO:6, or
B) SEQ ID NO:11/16.

These species are distinct because they differ in their structures; therefore each nucleic acid is patentably distinct.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is truly generic.

15. This application contains claims directed to the following patentably distinct species of the claimed Invention IV, XII and XXIII-XXVII: wherein the B7RP-1 polypeptide is:

A) SEQ ID NO:7, or
B) SEQ ID NO:12/17.

These species are distinct because they differ in their structures; therefore each polypeptide is patentably distinct.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is truly generic.

16. This application contains claims directed to the following patentably distinct species of the claimed Invention VI, XXVIII-XIX, XXI-XII and XXVIII-XXXII: wherein the antibody binds a B7RP-1 polypeptide that is:

A) SEQ ID NO:7, or
B) SEQ ID NO:12/17.

These species are distinct because they differ in their structures; therefore each antibody is patentably distinct.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is truly generic.

17. This application contains claims directed to the following patentably distinct species of the claimed Inventions XVII-XXII: wherein the IgE-mediated disorder is:

A) asthma, or

B) an allergic disorder.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 33 is generic.

18. This application contains claims directed to the following patentably distinct species of the claimed Inventions XXIII, XXV-XXVI, XXXIII and XXXV-XXXVI: wherein the disorder is:

A) cancer, or

B) a viral infection.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 42 is generic.

19. **If Applicant elects one of Groups XVII-XXII**, Applicant is further required to (1) elect a single disclosed species of each recited "antagonist" or combination thereof (having adequate support in the specification under 35 USC 112, first paragraph), for example, an antibody to the polypeptide of SEQ ID NO:2; to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

20. **If Applicant elects one of Groups XXVIII-XXXVII**, Applicant is further required to (1) elect a single disclosed species of each recited "agonist" or combination thereof (having adequate support in the specification under 35 USC 112, first paragraph) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

21. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

22. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
August 1, 2002

PHILLIP GAMBEL
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
8/1/02